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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,076	12/10/2003	Carlos A. Schuler	53286-US-CNT	7962

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
PATEL, NIHIR B	

ART UNIT	PAPER NUMBER
3772	

MAIL DATE	DELIVERY MODE
09/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,076	SCHULER ET AL.	
	Examiner	Art Unit	
	NIHIR PATEL	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *amendment filed on 06/05/2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

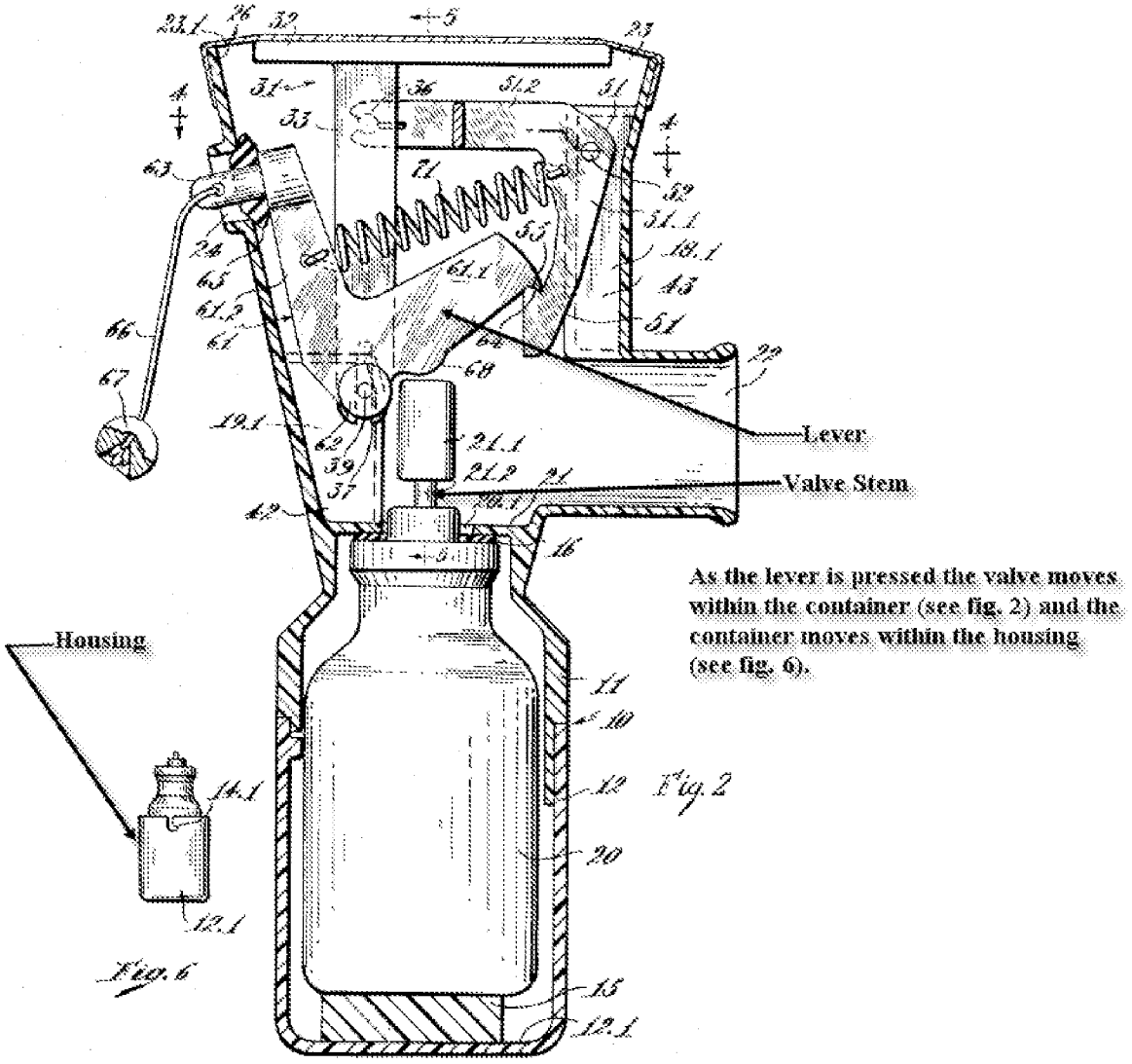
Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on June 5th, 2009 have been fully considered but they are not persuasive. In reference to claims 1-21, the applicant has one main argument that Kropp does not disclose a metering valve that is movable into a container when a user applied a force to the container and that the container moving within the housing. The examiner disagrees with the applicant's argument. Figures 2 and 6 shown below of the Kropp refernece discloses a metering valve that is movable into a container when a user applied a force to the container and that the container moving within the housing.



Response to Amendment

2. The examiner acknowledges the amendment filed on June 5th, 2009. The amendment comprises amending claims 1, 5, 10, 18-20, 22 and 26; and adding new claims 31 and 32.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims **1-32** are rejected under 35 U.S.C. 102(b) as being anticipated by Kropp (US 3,636,949).

5. **As to claim 1,** Kropp teaches an apparatus that comprises a housing **11 (see fig. 1 col. 3 lines 40-50)**; a container **20 (see fig. 2; col. 3 lines 50-60)** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant; a metering valve **21.1 (see fig. 2; col. 3 lines 50-60)** in communication with the reservoir, the metering valve being movable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing **(see figs. 2, 3 and 6; col. 4 lines 60-67 and col. 5 lines 1-5)**, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and a contact member **68** in the housing, the contact member being movable between a first position and a second position, wherein a portion of the metering valve is able to contact the contact member when the first position **(see fig. 3;**

col. 4 lines 25-35) and is unable to contact the contact member when in the second position **(see fig. 2; see col. 4 lines 60-70)**.

6. **As to claim 2,** Kropp teaches an apparatus wherein the metering vale may be moved to the actuated position only when the contact member is in the first position **(see figs. 2 and 3)**.

7. **As to claim 3,** Kropp teaches an apparatus wherein the container and the metering valve are movable within the housing and wherein when the contact member is in the first position, the metering valve is able to contact the contact member so that it may be moved into the container to the actuated position and when the contact member is in the second position, the metering valve is unable to contact the contact member and cannot be moved into the container to the actuated position **(see figs. 2 and 3; col. 4 lines 25-35 and lines 60-70)**.

8. **As to claim 4,** Kropp teaches an apparatus that comprises a controller adapted to selectively control the movement of the contact member **66 and 67 (the ball and cord define the controller that controls the movement of the contact member)**.

9. **As to claims 5 and 10,** Kropp teaches an apparatus that comprises a housing **11 (see fig. 1 col. 3 lines 40-50)**; a container **20 (see fig. 2; col. 3 lines 50-60)** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant; a metering valve **21.1 (see fig. 2; col. 3 lines 50-60)** in communication with the reservoir, the metering valve being movable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing **(see figs. 2, 3 and 6; col. 4 lines 60-67 and col. 5 lines 1-5)**, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and a contact member **68** in the housing, the contact member having a first configuration and a second configuration, wherein a portion of the

metering valve is able to contact the contact member when in the first configuration in a manner which allows the metering valve to be moved to the actuated position **(see figs. 2 and 3)**, and wherein a portion of the metering is able to contact the contact member when in the second configuration in a manner which does not allow the metering valve to be moved to the actuated position **(see figs. 2 and 3; because the contact member is controlled by the cord and ball and depends on the amount of pressure being applied to the ball or cord it is inherent that the a portion of the metering valve is able to contact the contact member when in the second configuration in a manner which does not allow the metering valve to be moved to the actuation position)**.

10. **As to claim 6,** Kropp teaches an apparatus wherein the metering valve may be moved to the actuating position only when the contact member is in the first position **(see figs. 2 and 3)**.

11. **As to claims 7 and 16,** Kropp teaches an apparatus wherein the container and the metering valve are movable within the housing and wherein when the contact member is in the first configuration, the metering valve is able to contact the contact member so that it may be moved into the container to the actuated position and when the contact member is in the second configuration, the metering valve is able to contact the contact member but cannot be moved into the container to the actuated position **(see figs. 2 and 3; because the contact member is controlled by the cord and ball and depends on the amount of pressure being applied to the ball or cord it is inherent that the a portion of the metering valve is able to contact the contact member when in the second configuration in a manner which does not allow the metering valve to be moved to the actuation position)**.

12. **As to claim 8,** Kropp teaches an apparatus wherein the contact member is rigid in the first configuration and is flexible in the second configuration **(see figs. 2 and 3).**

13. **As to claims 9, 17, 19 and 21,** Kropp teaches an apparatus that comprises a controller adapted to selectively control the movement of the contact member **66 and 67 (the ball and cord define the controller that controls the movement of the contact member)**.

14. **As to claim 11,** Kropp teaches an apparatus wherein the first condition is a first position and wherein the second condition is a second position **(see figs. 2 and 3)**.

15. **As to claim 12,** Kropp teaches an apparatus wherein the first position is a position in the housing where the contact member may contact a portion of the metering valve **(see figs. 2and 3)**.

16. **As to claim 13,** Kropp teaches an apparatus wherein the first condition is a first configuration and wherein the second condition is a second configuration, and wherein the first configuration is a rigid configuration **(see fig. 3).**

17. **As to claim 14,** Kropp teaches an apparatus wherein the second configuration is a relatively flexible configuration **(see fig. 2)**.

18. **As to claim 15,** Kropp teaches an apparatus wherein the metering valve may be moved to the actuating position when the contact member is in the first condition **(see fig. 2)**.

19. **As to claim 18,** Kropp teaches an apparatus that comprises a housing **11 (see fig. 1 col. 3 lines 40-50)**; a container **20 (see fig. 2; col. 3 lines 50-60)** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant; a metering valve **21.1 (see fig. 2; col. 3 lines 50-60)** in communication with the reservoir, the metering valve being movable into the container to an actuated position when a user applies a force to the container to cause the

container to move within the housing **(see figs. 2, 3 and 6; col. 4 lines 60-67 and col. 5 lines 1-5)**, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and a contact member **68** in the housing, wherein the metering valve may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member **(see fig. 3)** and may not be actuated when the metering valve and/or container is unable to contact the contact member **(see fig. 2)**.

20. **As to claim 20,** Kropp teaches an apparatus that comprises a housing **11 (see fig. 1 col. 3 lines 40-50)**; a container **20 (see fig. 2; col. 3 lines 50-60)** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant; a metering valve **21.1 (see fig. 2; col. 3 lines 50-60)** in communication with the reservoir, the metering valve being movable into the container to an actuated position when a user applies a force to the container to cause the container to move within the housing **(see figs. 2, 3 and 6; col. 4 lines 60-67 and col. 5 lines 1-5)**, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and a contact member **68** in the housing, wherein the metering valve may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member **(see fig. 3)** in a rigid configuration and may not be actuated when the metering valve and/or container is unable to contact the contact member is a rigid configuration **(see figs. 2and 3)**.

21. **As to claim 22,** Kropp teaches a method step of controlling the operation of an aerosolization device that comprises a container **20 (see fig. 2; col. 3 lines 50-60)** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant, and the aerosolization device comprising a metering valve in communication with the reservoir, the

metering valve **21.1 (see fig. 2; col. 3 lines 50-60)** being movable into the container to an actuated position when a user applies a force to the container to cause the container to move **(see figs. 2, 3 and 6; col. 4 lines 60-67 and col. 5 lines 1-5)**, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position, the method step comprising positioning a contact member in a first position where the contact member may contact the metering valve and/or the container to allow the metering valve to be moved to the actuation position **(see fig. 3)** and positioning the contact member in a second position where the metering valve may not be moved to the actuation position **(see fig. 2)**.

22. **As to claim 23,** Kropp teaches a method step wherein the second position is a position where the contact member may not be contacted by the metering valve or the container **(when the lever is not contacting the valve stem is defined as the second position)**.

23. **As to claim 24,** Kropp teaches a method step comprising returning the contact member to the first position after a condition is met **(the lever is returned to its position once the lever has been released)**.

24. **As to claim 25,** Kropp teaches a method step wherein the condition is the passage of a predetermined amount of time **(the time when the user releases the lever is defined a predetermined amount of time)**.

25. **As to claim 26,** Kropp teaches a method step of controlling the operation of an aerosolization device that comprises a container **20 (see fig. 2; col. 3 lines 50-60)** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant, and the aerosolization device comprising a metering valve in communication with the reservoir, the

metering valve **21.1 (see fig. 2; col. 3 lines 50-60)** being movable into the container to an actuated position when a user applies a force to the container to cause the container to move **(see figs. 2, 3 and 6; col. 4 lines 60-67 and col. 5 lines 1-5)**, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position, the method step comprising configuring a contact member in a first configuration wherein the contact member may contact the metering valve to allow the metering valve to be moved to the actuated position **(see fig. 3)**; and configuring the contact member in a second configuration wherein the metering valve may n contact the contact member but may not be moved to the actuated position **(see figs. 2 and 3; because the contact member is controlled by the cord and ball and depends on the amount of pressure being applied to the ball or cord, therefore it is obvious that the a portion of the metering valve is able to contact the contact member when in the second configuration in a manner which does not allow the metering valve to be moved to the actuation position)**.

26. **As to claim 27,** Kropp teaches a method step wherein the first configuration is a rigid configuration **(the fact that the lever is held in place by a spring it is defined as a rigid configuration; see fig. 2)**.

27. **As to claim 28,** Kropp teaches a method step wherein the second configuration is flexible configuration **(the fact that the spring expands when the lever is pressed is defined as a flexible configuration)**.

28. **As to claim 29,** Kropp teaches a method step comprising returning the contact member to the first configuration after a condition is met **(the lever is returned to its position once the lever has been released)**.

29. **As to claim 30,** Kropp teaches a method step wherein the condition is the passage of a predetermined amount of time **(the time when the user releases the lever is defined a predetermined amount of time)**.

30. **As to claims 31 and 32,** Kropp teaches an apparatus wherein the container moves within the housing when a force is applied by the user directly to a surface of the container **(the valve nozzle 21.1 and the valve stem 21.2 are part of the container specifically the top surface of the container and therefore the container moves within the housing (see fig. 6) when a force is applied by the user (pulling down the lever) directly to a surface of the container (valve nozzle and stem))**.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772